EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Departmental Appeals Board, MS 6127
Medicare Appeals Council
330 Independence Avenue
Cohen Building, Room G-644
Washington, DC 20201
(202)565-0100/Toll Free:1-866-365-8204

Date: JAN 22 2020

ALJ Appeal Numbers: 1-7884275431 & 16 others
Docket Numbers: M-19-1261 & 30 others

ACKNOWLEDGMENT OF ESCALATION REQUESTS
AND NOTICE OF STAY

Parrish Law Offices
Debra Parrish
788 Washington Rd.
Pittsburgh, PA 15228

Dear Ms. Parrish:

The Medicare Appeals Council (Council) has received your requests to escalate the appeals listed in Attachment A to Federal district court. The Council previously received your requests for review for these appeals. The 90-day time frame for the Council to issue a decision, dismissal, or remand order has expired. *See* 42 C.F.R. § 405.1100(c). Due to the large number of pending appeals, the Council is unable to issue a decision, dismissal, or remand order within five calendar days of your request to escalate to Federal district court. 42 C.F.R. § 405.1132(a)(1). Under these circumstances, the regulations permit you to bypass Council review and seek review of the ALJ's decisions in Federal district court. 42 C.F.R. § 405.1132(a)(2).

In order to escalate, you must file an action in Federal district court within 60 calendar days after you receive this notice and the amount in controversy must be $1,670 or more. 42 C.F.R. §§ 405.1132(b), 405.1136(a)(1); *see also* 84 Fed. Reg. 53,445 (Oct. 7, 2019). If you cannot file your complaint within 60 days, you may ask the Council to extend the time in which you may begin a civil action. However, the Council will only extend the time if you provide a good reason for not meeting the deadline. Your reason must be set forth clearly in your request. 42 C.F.R. § 405.1134. If you do not file an action in Federal district court, then your appeals will remain before the Council. 42 C.F.R. § 405.1136(a)(2).

If a civil action is commenced, the complaint should name the Secretary of Health and Human Services as the defendant and should include the Council docket numbers and ALJ appeal numbers that you are appealing. 42 C.F.R. § 405.1136(d). The Secretary must be served by sending a copy of the summons and complaint by registered or certified mail to the General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201. In addition, you must serve the United States Attorney for the district in which you file your complaint and the Attorney General of the United States. *See* rules 4(c) and (i) of the Federal Rules of Civil Procedure and 45 C.F.R. § 4.1.

Additionally, the supplier filed a separate request for review in each of the appeals for which you seek escalation. *See* Attachment B. This letter serves as notice to all parties that the Council will stay the supplier's requests for review until the Federal district court issues a final determination on the escalated appeals or the time period for filing a complaint in district court expires.

Sincerely,

Angela K. Roach
Administrative Appeals Judge

cc: Novocure
Beneficiaries

PARRISH LAW OFFICES

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Pittsburgh, Pennsylvania 15228-2021
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412.561.6250
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December 31, 2019

VIA E-file

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, DC 20201

RE: Request for Escalation
Appellant/Medicare Beneficiary: Robert Townsend
HICN: 094523358A
ALJ Decision Date: June 25, 2019
ALJ Appeal No.: 1-8429561876
DOS: 8/7/18 through 10/7/18
Council No.: M-19-2499 (filed Aug. 14, 2019)
Our Ref: 19-113

Dear Medicare Appeals Council:

Mr. Townsend has received a third favorable ALJ decision finding TTFT meets Medicare coverage criteria for him. See ALJ 1-8637672132. The Secretary chose not to appeal the decisions, and each of them has become final. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues with respect to Mr. Townsend. As noted by a unanimous Supreme Court, "We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality." *See Astoria Federal Savings and Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). The application of issue preclusion would not work as basic unfairness against the Secretary and there are no special circumstances that would make it unfair to apply the doctrine.

The above-captioned Medicare beneficiary appeal has been pending for more than 90 days. Accordingly, pursuant to 42 C.F.R. §405.1132, Mr. Townsend requests escalation of the above-captioned claims to District Court.

Sincerely,

Debra M. Parrish

Debra M. Parrish for
Medicare Beneficiary Robert Townsend

Enclosure: Third Final Favorable Decision
cc: Robert Townsend
Novocure
C2C

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

RECEIVED AUG 19 2019

19-308

Seattle Field Office
700 Stewart Street, Suite 11101
Seattle, WA 98101
206-539-5300 (Main)
206-539-5376 (ALJ Gates Team)
206-553-0122 (Fax)
844-556-2949 (Toll Free)

Date: AUG 15 2019

PARRISH LAW FIRM
ATTN: DEBRA PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: R. TOWNSEND
OMHA Appeal Number: 1-8637672132

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may TFTT an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod.**

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review
OMHA-101, Notice of Nondiscrimination

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Seattle, Washington

Appeal of:	**R. TOWNSEND**	OMHA Appeal No.:	**1-8637672132**
Beneficiary:	**R. TOWNSEND**	Medicare:	**Part B**
Medicare No.:	*******3358A**	Before:	**Timothy Gates** Administrative Law Judge

DECISION

After carefully considering the record, a **FAVORABLE** decision is issued in the appeal of R. Townsend (Appellant).

Procedural History

Novocure Inc. (Supplier) submitted assigned Medicare claims for an electronic stimulation device (E0766) it provided to R. Townsend (Beneficiary) during dates of service November 7, 2018, December 7, 2018, and January 7, 2019 (Dates of Service). Noridian Healthcare Solutions, LLC (Noridian), DME Medicare Administrative Contractor (MAC) Jurisdiction A, denied coverage upon initial determination and again upon redetermination review. (Exh. 1, pp. 23-26). On June 7, 2019, the Medicare Qualified Independent Contractor (QIC), C2C Innovative Solutions, Inc., issued an unfavorable reconsideration decision, upholding the prior denials of coverage. (Exh. 1, pp. 1-11).

On June 19, 2019, the Office of Medicare Hearings and Appeals (OMHA) received Appellant's timely Request for Medicare Hearing by an Administrative Law Judge (ALJ). (Exh. 3, pp. 1-2, 6). The Appellant submitted additional evidence which was admitted into the record in accordance with 42 C.F.R. § 405.1018(d)(2). (Exh. 5). The amount in controversy satisfies the jurisdictional requirement for an ALJ hearing pursuant to Title XVIII of the Social Security Act (Act) § 1869(b)(1)(E).

Pursuant to proper notice, a telephonic hearing was held on July 30, 2019, from the OMHA Seattle Field Office. Debra Parrish, Esq. appeared on behalf of the Appellant. (Exh. 4, p. 13). Timothy Parks, RN, Clinical Director for Novocure, testified as a witness. (Exh. 4, p. 14; Hearing Testimony). Exhibits 1 through 5 were admitted into the record without objection.

Issues

Whether Medicare Part B covers the electronic stimulation device (E0766) furnished to the

Appellant/Beneficiary on the Dates of Service and if not, whether § 1879 of the Act may limit liability for any non-covered items or services at issue.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

The Beneficiary, a 54 year old male born on January 20, 1964, was diagnosed with glioblastoma with primitive neuro ectodermal tumors (PNET) in November 2011. (Exh. 2, p. 4). Temozolomide chemoradiation in February 2012 was complicated by generalized seizures experienced by the Beneficiary. (*Id.*) He presented to the hospital in December 2012 with progressive left-sided weakness and non-paroxysmal confusion; an MRI revealed a right-frontal resection cavity with heterogeneous enhancement. (*Id.*) A computerized tomography (CT) scan in May 2013 showed a left inguinal node had increased in size, and it was excised in July 2013 which revealed recurrent adenocarcinoma. (*Id.*) CT scan in August 2014 was clear of the recurrent tumor. (*Id.*) The Beneficiary was treated with bevacizumab from January to May 2013, and temozolomide monthly from January to May 2013 and daily from June to November 2013. (*Id.*) He began Optune, a tumor treatment field therapy (TTFT) device, in May 2014 with clinical and radiographic response. (*Id.*) The Beneficiary's treating physician, Samuel Goldlust, MD, noted that the treatment was well tolerated though compliance was less than goal. (*Id.*) Dr. Goldlust reviewed the serial brain magnetic resonance imagining (MRI) scans; in comparison to pre-treatment imaging from April 23, 2014, the images from July 23, 2014 and October 22, 2014 demonstrate serially improved enhancing burden, and stable condition was reflected in the images from February 15, 2015, May 17, 2015, October 22, 2015, February 16, 2016, June 15, 2016, October 18, 2016, minimally evolved in February 16, 2017, and stable on June 15, 2017, October 19, 2017, and March 22, 2018.

The Beneficiary was initially prescribed the TTFT on April 30, 2014. (Exh. 2, p. 2). The prescription was renewed on August 16, 2018 by Dr. Goldlust on the Supplier's form. (Exh. 2, p. 1). The Beneficiary signed the Optune Service Agreement on May 17, 2016. (Exh. 2, pp. 14-25).

Dr. Goldlust submitted a letter in regard to Medicare coverage appeals on July 11, 2016. (Exh. 1, p. 83). He stated that Optune is a novel therapeutic modality in cancer treatment, and he stated that TTFT interferes with tumor cell division via interruption of mitosis, leading to programmed cancer cell death. (*Id.*) Further, clinical trials, leading to the FDA approval of this device in 2011, demonstrated that for recurrent GBM, Optune has comparable efficacy to chemotherapy with a more favorable toxicity profile and improved quality of life. (*Id.*) Dr. Goldlust also noted that coverage for this device has been approved, based on medical director review, physician to physician review, or outside review by a number of insurance companies, large and small across the country. (Exh. 1, p. 84).

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) approved the Supplier's premarket approval application supplement for Optune in October 2015. The device is indicated as a treatment for adult patients (22 years of age or older) with historically-confirmed glioblastoma multiforme (GBM). Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. Optune was previously approved in 2011 for the treatment of

recurrent GBM with the following Indications for Use (IFU): Optune is indicated following histologically, or radiologically, confirmed recurrent in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. (Exh. 1, p. 77).

Peer-reviewed literature suggest that tumor-treating fields, also known as alternating electric fields, disrupt the cell division process in cancerous tumors which may lead to programmed cell death, or apoptosis. Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in GBM brain tumors compared with traditional standards of care alone. (Exh. 1, pp. 87-99).

A large number of health care insurance providers have medical policies in place allowing coverage for the device for TTFT of GBM when certain conditions are met. These providers include, but are not limited to, AETNA, Highmark, Anthem, Humana, Kaiser, United Healthcare, Cigna, Geisinger, and Blue Cross Blue Shield. (Exh. 1, p. 84).

Noridian has issued a future Local Coverage Determination L34823 for Tumor Treatment Field Therapy (TTFT), revision effective date for services performed on or after September 1, 2019, allowing Medicare coverage for treatment for newly diagnosed glioblastoma multiforme if certain conditions are met. (Exh. 5, pp. 34-54).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Act § 1869(b)(1)(A); 42 C.F.R. § 405.1014. In implementing the statutory directive, the Secretary delegated the authority to administer the nationwide hearings and appeals systems for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). ALJs in OMHA issue final decisions of the Secretary, excluding decisions reviewed by the Medicare Appeals Council (*Id).*

For requests filed in calendar year 2019, the minimum amount in controversy required for an ALJ hearing is $160.00 (after applying applicable co-insurance and deductibles). *See* Act § 1869(b)(1)(E); *see also* 42 C.F.R. § 405.1006; *see also* 83 Fed. Reg. 47619 (Sep. 20, 2018).

To be considered timely, the request for hearing must be received by OMHA within 60 days after the Appellant receives the QIC's reconsideration decision. The Appellant is presumed to have received the QIC's reconsideration decision five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. §§ 405.1002 and 405.1014.

B. Scope of Review

The issues before the ALJ include all issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the appellant's favor. 42 C.F.R. § 405.1032(a). If evidence presented before a hearing causes an ALJ to question a favorable portion of a determination, the ALJ may notify the parties before the hearing and consider it an issue at the hearing (*Id.*).

C. Standard of Review

The ALJ conducts a *de novo* review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedure Act (APA). *De novo* review means the ALJ independently assesses evidence without regard to prior findings made on the claim and makes an independent assessment based upon applicable law and policy. The burden of proving each element of a Medicare claim lies with the appellant by preponderance of the evidence (i.e., is satisfied by submitting sufficient evidence in accordance with program requirements). *See* Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

A. Statutes and Regulations

Section 1831 of the Act establishes the Supplemental Medical Insurance Program for the aged and disabled under Part B. Act § 1831. Section 1832 of the Act establishes the scope of benefits that are provided to beneficiaries under the Medicare Part B insurance program. Act § 1832; *see also* 42 C.F.R. §410.3. Under §1832(a)(2)(B) of the Act, an individual is entitled to have payment made on his/her behalf for medical and other health services furnished by a provider of services or by others under arrangement with them made by a provider of services. Act § 1832(a)(2)(B).

Section 1833(e) of the Act states that no payment can be made to the provider or another person unless such information, as may be necessary, has been furnished in support of the medical necessity of the claimed services in order to determine the amount due such provider or other individual. Act § 1833(e); *see also* 42 C.F.R. § 424.5(a)(6).

Section 1834 of the Act defines the rules for payment of covered items of durable medical equipment. Act § 1834.

Section 1861(s) of the Act defines "medical and other health services" to include physician services and services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B). Act § 1861(s).

Section 1861(s)(9) of the Act defines the term "medical and other health services" to specifically include durable medical equipment, including leg, arm, back, and neck braces, and artificial legs,

arms, and eyes, including replacements if required because of a change in the patient's physical condition. Act § 1861(s); *see also* 42 C.F.R. § 410.10(h).

Section 1862(a)(1)(A) of the Act provides that notwithstanding any other provision of the Act, no payment shall be made for any expenses incurred for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A).

Section 1879 of the Act provides in pertinent part the liability of the beneficiary and/or provider of services may be waived in cases where payment is not made by reason of sections 1862(a)(1) or (9), if the beneficiary or provider did not know or could not be reasonably expected to have known that the care was not covered.

B. Policy and Guidance

The Medicare program is administered through the Centers for Medicare and Medicaid Services (CMS), a component of the United States Department of Health and Human Services. Under the authority of Section 1842(a) of the Act, the Secretary of the Department of Health and Human Services is authorized to enter into contracts with private entities for the day-to-day operations of the program. Act § 1842(a). In order to further implement the Act, CMS issued National Coverage Determinations (NCDs). Pursuant to section 1869(f)(1)(A)(i) of the Act, an ALJ may not set aside or review a NCD. Act § 1869(f)(1)(A)(i). As such, the ALJ must follow the criteria for coverage set out by the NCD as it applies to the particular case. Relevant to the case at hand is NCD 40.2 for Home Blood Glucose Monitors.

Section 1871(a)(2) of the Act states that "[n]o rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation." Act § 1871(a)(2); *see also* 42 C.F.R. § 405.1060. In lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations (LCDs), respectively.

Although ALJs are not bound by LCDs or CMS program guidance, such as program memoranda and manual instructions, an ALJ will give substantial deference to these policies if they are applicable to a particular case. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect. 42 C.F.R. § 405.1062(b). The authority to promulgate manuals and other policy issuances is found, in part, in Section 1842 of the Act.

As relevant herein, Noridian Healthcare Solutions, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (TTFT) (LCD L34823) (effective Jan. 1, 2017 through Aug. 31, 2019) specifies coverage criteria as:

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

•The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.

•The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

•Refer to the Supplier Manual for additional information on documentation requirements.

•Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

The primary issue on appeal is whether Medicare Part B coverage should be provided for electronic stimulation device (E0766) for the Dates of Service. The QIC found that based on the available documentation, the requirements of the LCD and CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08)* have not been met, and therefore, the claims cannot receive reimbursement. (Exh. 1, p. 10).

In its unfavorable reconsideration decision, the QIC stated "LCD L34823 details that TTFT (E0766) will be denied as not reasonable and necessary. This LCD remains in effect until such time the DME MAC retires the non-coverage LCD or a new LCD becomes effective. Therefore, in accordance with the aforementioned LCD, the claim for TTFT services is determined to be not reasonable or necessary." (*Id.*) Further, the QIC noted that it had reviewed the National Comprehensive Cancer Network (NCCN) guidelines and the medical literature and found the medical documentation of the efficacy of the device was not within the usual scope and breadth of

current medical literature with peer acknowledgment and review. (*Id.*) Specifically, the QIC found the literature and clinical trials to be limited in number and the clinical trials were not non-biased. (*Id.*)

The LCD that addresses TTFT, L34823, specifically denies coverage. It states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The LCD does not provide any circumstances under which TTFT would be covered.

The Beneficiary in this case was diagnosed with GBM and received initial treatment with radiation and chemotherapy. (Exh. 2, p. 4). He started treatment with the electronic stimulation device (E0766) in 2014 and MRI scans showed treatment response. (*Id.*) The device is reimbursed by Medicare on a monthly basis. In this appeal, the Appellant seeks Medicare coverage for the device furnished to him on November 7, 2018, December 7, 2018, and January 7, 2019 (Dates of Service).

While LCD L34832 was appropriately considered at the lower levels in making the decision to deny the TTFT in this case based upon the unambiguous pronouncement that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary," I decline to follow that statement in the LCD. The Code of Federal Regulations identifies the applicability of Local Coverage Determinations. It states that LCDs are required to be adhered to by Medicare contractors. 42 C.F.R. § 405.1062. However, the ALJs and the Medicare Appeals Council are not bound by LCDs. If an ALJ declines to follow an LCD in a particular case, he or she may do so, but must explain why the policy was not followed. (*Id.*)

In this case, the Appellant has provided evidence which clearly establishes TTFT is safe and effective for its intended use in patients with newly-diagnosed and recurrent GBM. The record contains documentation showing the device received FDA pre-market approval for patients with recurrent GBM in 2011 and pre-market approval for patients with newly diagnosed GBM in October 2015. (Exh. 1, p. 77). While pre-market approval from the FDA does not establish that the device is reasonable and necessary pursuant to Medicare requirements, the approvals reflect that the FDA determined sufficient scientific evidence exists to show the device was safe and effective for its intended use in patient with newly-diagnosed and recurrent GBM.

The record further shows TTFT has broad acceptance in the medical community as a safe and effective treatment for GBM. The record contains a letter from Dr. Goldlust, the Beneficiary's treating physician, which states the efficacy of the treatment and its wide acceptance in the medical community. (Exh. 1, pp. 83-84). The peer-reviewed literature shows that tumor treating fields disrupt the cell division process in cancerous tumors which may lead to programmed cell death. Tumor treating fields have also shown statistically significant improvement in patient survival rates and outcomes in GBM brain tumors when compared with traditional standard of care alone. Additionally, Mr. Timothy Parks, a Registered Nurse employed by the Supplier who has a great deal of familiarity with TTFT, offered credible testimony concerning the effectiveness of the device in treating GBM, the compliance rates for efficacy, and the positive results experienced by the Beneficiary from treatment. (Hearing Testimony).

Furthermore, regarding the number of clinical trials, I am persuaded by Appellant's argument that a "limited number" of clinical trials is common when a treatment is proven effective for a fatal condition, and, because the treatment is so effective, the FDA deemed it unethical to continue a

study that withheld such an effective treatment from those battling a fatal disease, as GBM is considered an orphan disease with a high mortality rate. (Exh. 1, p. 20).

I find that TTFT is not experimental in nature. The pre-market approvals, peer-reviewed medical literature, credible letter from Dr. Goldlust, and credible testimony from Mr. Parks establish that the device is not experimental and has gained wide-spread acceptance in the medical community. In summary, the evidence presented in this case supports the conclusion that the device is not experimental in nature.

For these reasons, I decline to follow the LCD. The FDA approval of TTFT, the overwhelming medical research evidence, and the written statement by the Beneficiary's physician articulate that TTFT is effective in extending the lives of patients who have been newly diagnosed or have recurrent glioblastoma. It is no fault of the Medicare contractors for coming to a different conclusion as they adhered to the pronouncement in the LCD. However, if there was a reason for an ALJ to vary from the strict, unexplained restriction in an LCD, it is this case where the very life of the Beneficiary hangs in the balance, with very few, if any, other medical options to treat him and prolong his life aside from the treatment provided by the TTFT device. Therefore, I find that the record clearly establishes that the device is medically reasonable and necessary to treat the Beneficiary's condition.

As this decision is favorable to the Appellant, the limitation on liability provisions of Section 1879 of the Act are not triggered.

Conclusions of Law

The electronic stimulation device (E0766) furnished to the Appellant/Beneficiary on the Dates of Service is reasonable and necessary under Section 1862 of the Act and is covered by Medicare.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: AUG 15 2019

Timothy Gates
Administrative Law Judge

PARRISH LAW OFFICES

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August 14, 2019

VIA MEDICARE OPERATIONS DIVISION E-FILE

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building, Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Re: ALJ Appeal No.: 1-8429561876
Decision Date: June 25, 2019
Appellant: R. Townsend
Beneficiary: R. Townsend
HICN: 094523358A
Dates of Service: 8/7/18, 9/7/18, 10/7/18
Service: E0766
Our Ref: 19-113

Dear Medicare Appeals Council:

Robert Townsend hereby appeals the attached June 25, 2019 unfavorable decision by Administrative Law Judge Brian Butler with respect to the above-identified case. See Attachment 2. Appellant appeals the unfavorable portion of the decision based on mistake of fact and mistake of law.

I. The issues to be considered in the appeal are:

1. Did the ALJ make a mistake of law when he failed to apply the principle of collateral estoppel?

2. Did the ALJ make a mistake of law when he failed to give *de novo* review of the evidence in a particular case?

3. Did the ALJ make a mistake of law when he applied future LCD coverage criteria?

4. Should the ALJ's decision be vacated in view of the invalidity of the LCD?

5. Was TTFT reasonable and medically necessary, and entitled to Medicare coverage when prescribed for Mr. Townsend?

II. Introduction

Glioblastoma (GBM) is the most aggressive form of cancer that begins in the brain and is extremely lethal. Without treatment, survival is typically three months. With treatment (but not with the Optune system), survival is typically 12-15 months and only 3-5% of patients survive longer than 5 years. For individuals diagnosed with recurrent GBM, the life expectancy is six months.

Mr. Townsend was prescribed an Optune system for his recurrent brain cancer (GBM) in May 2014. The Optune system delivers tumor treatment field therapy (TTFT). TTFT creates an electrical field that disrupts and corrupts the division of cancer cells and leads to the death of such cells. In 2011 and 2015, the FDA approved, through its more rigorous review process, the Optune device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. The initial FDA approval was for recurrent glioblastoma. The FDA then approved the Optune device for newly diagnosed glioblastoma. See October 5, 2015 letter on CD attached to request for hearing. During the clinical trial for newly diagnosed glioblastomas, the interim TTFT results were so compelling (i.e., the treatment was able to show significant clinical benefit) that the Data Safety Monitoring Board recommended early termination of the study to enable patients not receiving the treatment to cross over and receive the treatment, deeming it to be unethical to withhold TTFT from those not receiving it. The FDA agreed.

All the claims at issue were denied by the contractor citing LCD L34823 which simply states: "TTFT will be denied as not reasonable and necessary." The QIC also denied the claims citing the LCD and finding that the studies were insufficient. On May 28, 2019, the Civil Remedies Division ruled the LCD record did not support the validity of the LCD under the reasonableness standard. On July 18, 2019, the DMACs revised LCD L34823. The revision of an LCD after an LCD challenge has been filed has the same effect as a judicial ruling that the LCD was invalid. See 42 C.F.R. §426.420.

III. Satisfaction of Medicare Coverage Criteria

Before turning to the ALJ's decision, and the errors therein, whether TTFT should be covered applying normal coverage rules is addressed.

All of the claims initially were denied by the Medicare contractor on the basis that TTFT was not reasonable and medically necessary generally and that the peer-reviewed literature does not document the effectiveness of the device. With respect to the second point, the evidence to the contrary is overwhelming. The data from the clinical trial for newly diagnosed glioblastomas demonstrated such remarkable effectiveness that the study was terminated early to enable those not receiving treatment during the clinical trial to receive the treatment. The FDA approved the device as effective. Because the peer-reviewed literature is so compelling, TTFT is included in the NCCN guidelines, i.e., uniform agreement exists among the experts that TTFT should be

offered to those with recurrent glioblastoma. Unfortunately, LCD L34823 did not reflect consideration of any studies after 2014 including two landmark papers in JAMA, one of which included outcomes for individuals who had recurrent GBM.

TTFT satisfies the other two coverage criteria – the consensus of experts and widespread adoption. The consensus of experts (reflected in the NCCN guidelines and adoption by all the major medical centers in the United States), and acceptance by the relevant medical community (again in view of the inclusion in practice guidelines, the device has been prescribed in every state by hundreds of clinicians and is covered by all major payers), strongly support Medicare coverage.

The ALJ should have undertaken the foregoing analysis, which he did not. Accordingly, there is not substantial evidence to support a coverage denial, especially here where the Optune system is the standard of care. A policy that conflicts with the standard of care must be based on convincing evidence. The only evidence of record is that the Optune system was and is medically reasonable and necessary for Mr. Townsend.

IV. Errors of Law and Fact

Turning to the ALJ's decision, the ALJ denied coverage on the basis of LCD L34823. That was in error.

A. Collateral Estoppel

Medicare coverage of TTFT for Mr. Townsend previously, repeatedly and explicitly has been found. See ALJ Nos. 1-7737575148 and 1-8116629727. These two prior favorable ALJ decisions are for other dates of service for the same device for the same condition. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues. As noted by a unanimous Supreme Court:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

See Astoria Federal Savings and Loan Assoc. v. Solimino, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). No basis exists for the Secretary to ignore the prior coverage rulings for this Medicare beneficiary. Accordingly, coverage of Mr. Townsend's TTFT device should be ordered.

B. Proper Review/Consideration of an LCD

On May 28, 2019, the Civil Remedies Division ruled that the LCD record did not support the validity of the LCD under the reasonableness standard. On July 18, 2019, the DMACs issued a revision of LCD L34823. Under 42 C.F.R. §426.420, the revision of an LCD after a challenge has been filed has the same effect as a judicial ruling that the LCD was invalid. On this basis alone, Judge Butler's decision should be vacated.

Regardless of the invalidation of the LCD, when considering an individual appeal of a coverage denial, an ALJ is not bound by an LCD. See 42 C.F.R. § 405.1062(a). Instead, an ALJ must merely give substantial deference to it and explain his reasons should he decline to follow an LCD in a particular case. See 42 C.F.R. § 405.1062(b). An ALJ's decision to decline to follow an LCD in a particular case has no precedential effect and does not result in the setting aside or invalidity of an LCD. See 42 C.F.R. § 405.1062(b). An ALJ's decision on whether to apply an LCD to a particular case is based on the facts/arguments presented in that case. Of course, Medicare beneficiaries are entitled to an individualized consideration of their appeals by an ALJ on a *de novo* basis. See 42 C.F.R. § 405.1000(d). Accordingly, rather than being precluded from reviewing whether an LCD should apply to a particular case, ALJs have a duty to determine just that.

In the present case, Mr. Townsend asked the ALJ to consider his case *de novo*, based on the facts of the case, and the arguments presented and determine whether LCD L34823 should be deferred to. The ALJ however, however noted the LCD was still effective and a revision of the LCD would still not cover recurrent GBM and that Mr. Townsend's use did not comply with future coverage criteria. The ALJ should not have applied the invalid LCD and was precluded from applying future coverage criteria.[1] That was an error of fact/law.

C. Failure to Comply With 42 C.F.R. § 405.1062(a)/(d)

As noted above, ALJs are not bound by LCDs and only give deference to them. See 42 C.F.R. § 405.1062(a). Further, ALJs are commanded to conduct a *de novo* review of the case. See 42 C.F.R. § 405.1062(d). Accordingly, there must be some fact(s) that a beneficiary could present that would cause the ALJ to not defer to an LCD. To hold otherwise would contradict the command of § 405.1062(a).

In the present case, Mr. Townsend presented evidence that, *after LCD L34823 issued*:

[1] Although the peer reviewed literature supports coverage if TTFT is used 12 hours a day, the future LCD requires 18 hours per day unless a reason for lower use is documented. Clearly Mr. Townsend and his clinician could not have anticipated a requirement to document the skin irritations that often are the cause of lower utilization.

1) Published studies demonstrated the conclusive safety and effectiveness of TTFT;
2) The consensus of experts is that TTFT is safe and effective;
3) A clinical trial of TTFT was halted because it would have been unethical to deny TTFT to the study participants that were not selected for treatment (this trial included both newly diagnosed and recurrent GBM); and
4) TTFT became the standard of care for newly diagnosed GBM.

Of course, Mr. Townsend also presented evidence of his own medical condition. Mr. Townsend had a life expectancy of six months, but has lived more than five years since using TTFT. His extraordinary medical benefit and outcome would have warranted coverage.

In his decision, the ALJ ignored the foregoing and simply stated the LCD was in effect. Respectfully, the ALJ's reasoning in this regard reflects an error in both the evidence on which an ALJ's decision is to be based, and the ALJ's role in the process. As prescribed by 42 C.F.R. § 405.1000(d), an ALJ's decision is based on the "administrative record", i.e., the record in the specific case. Thus, the ALJ should have considered the invalidity of the LCD, the Medicare beneficiary's condition and the overwhelming evidence that TTFT met Medicare's coverage criteria before the dates of service.

In the present case, Mr. Townsend offered evidence that TTFT had conferred a specific benefit to him, and is, literally, a life-saving treatment for his deadly form of brain cancer. The ALJ's refusal to consider that evidence was an error of law.

V. Conclusion

The Optune system was reasonable and medically necessary when it was provided to Mr. Townsend. The denial is contrary to the facts and law. The ALJ committed fundamental errors of law when he denied a Medicare beneficiary coverage of a service which has extended his life and applied an LCD that was invalid. Based on the foregoing, the Council should reverse Judge Butler's decision and order coverage of the Optune system for Mr. Townsend consistent with the prior ALJ decisions and the standard of care.

Please contact me if you have any questions regarding this appeal.

Yours very truly,

Debra Parrish TTAT

Debra Pistorino Parrish

Enclosures:
Attachment 1: Appointment of Representative [UPLOADED TO DAB E-FILE]
Attachment 2: June 25, 2019 ALJ Decision [UPLOADED TO DAB E-FILE]
Attachment 3: Prior ALJ Decisions

cc: R. Townsend
Novocure, Inc.
C2C Innovative Solutions, Inc.

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Kansas City Field Office
601 East 12th Street, Suite 221
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Date: November 8, 2018

DEBRA M PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: R. TOWNSEND
OMHA Appeal Number: 1-7737575148

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod.**

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

R. TOWNSEND

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	**R. Townsend**	ALJ Appeal No.:	**1-7737575148**
Enrollee:	**R. Townsend**		**Medicare Part B**
HICN:	*******3358A**	Before:	**David Krane** U.S. Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the hearing and record, this Administrative Law Judge ("ALJ") enters a **FULLY FAVORABLE** decision for the beneficiary, R. Townsend ("Beneficiary").

Procedural History

The Beneficiary was prescribed Optune tumor treatment field therapy ("TTFT"), manufactured by NovoCure, Ltd. ("Supplier"), for treatment of glioblastoma for dates of service August 7, 2017, September 7, 2017, and October 7, 2017. At initial determination and redetermination, the Medicare Administrative Contractor ("Contractor") with jurisdiction denied coverage. The decision was appealed and the Qualified Independent Contractor ("QIC") issued an unfavorable reconsideration decision on June 22, 2018. (Exh. 1, pp. 1-4).

On August 2, 2018, the Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's timely request for an ALJ Hearing. 42 C.F.R. § 405.1014(b)(1). An administrative hearing was held by telephone on October 11, 2018. The Beneficiary appeared through Debra M. Parrish, Esq., Counsel for the Beneficiary; Julie Miles, R.N., Clinical Appeals Specialist with the Supplier; and Tim Parks, R. N., Clinical Appeals Specialist with the Supplier, who observed the proceedings. The Beneficiary's representatives testified under oath.

In the request for hearing, the Beneficiary requested consolidation of additional appeals pending for OMHA. This ALJ declines to hold a consolidated hearing on this and other pending appeals concerning the Beneficiary. It is not clear from the record that the additional appeals pending before OMHA were filed by the same appellant. 42 C.F.R. § 405.1044. Further, some of these appeals have already been assigned to other ALJs and consolidating the appeals at this point would negatively impact the orderly adjudication of appeals.

At the ALJ level of appeal, the Beneficiary submitted a position paper and a compact disc containing clinical studies, prior favorable ALJ decisions, and FDA approval letters, among other documents. Because the Beneficiary is represented by someone other than a provider or supplier, no good cause statement explaining why the evidence was not previously submitted to the QIC is required. As such, this ALJ admits the evidence as Exhibit 5. Exhibits 1 through 5 were admitted into evidence without objection and have been considered by the ALJ in reaching this decision. This ALJ carefully considered the hearing testimony, argument and record.

Issues

The issues before the ALJ include all of the issues brought out in the initial determination, coverage determination, or organization determination; redetermination; or reconsideration that were not decided entirely in a party's favor, for the claims or other appealed matters specified in the request for hearing.

Findings of Fact

After careful consideration of the entire record (Exhibit List attached and incorporated herein), a preponderance of the evidence establishes the following facts:

All jurisdictional requirements of this case have been met.

At redetermination, the Contractor explained that the Local Coverage Determination L34823 states that TTFT (E0766) will be denied as not reasonable and necessary. (Exh. 1, p. 40). The QIC determined that insufficient documentation was found in the record to quantify the effects of the device for this Beneficiary. (Exh. 1, p. 4). Additional records were not submitted to explain why this particular Beneficiary should be considered for the treatment. *Id.* Therefore, based on the documentation available, the requirements of the LCD were not met. *Id.*

The Beneficiary was a 53-year-old male on the dates of service. (Exh. 2, pp. 35-36). According to physician progress notes from February 16, 2017, the Beneficiary was diagnosed with right-frontal glioblastoma multiforme with primitive neuroendocrine tumor features in late 2011. *Id.* Resection of the tumor was completed on November 28, 2011, at Bellevue. *Id.* Chemoradiation using temozolomide in February 2012 was reported to be complicated by generalized seizure. *Id.* The February 16, 2017, progress notes indicated that the Beneficiary was then lost to follow up and later presented in December 2012 with left-sided weakness and non-paroxysmal confusion. *Id.*

An MRI performed in December 2012, showed the right frontal resection cavity and surrounding heterogeneous enhancement. (Exh. 2, pp. 35-36). In May 2013, a chest CT showed a left inguinal node that had increased in size and was mildly PET avid. *Id.* This node was excised on July 9, 2013, and showed recurrent adenocarcinoma. *Id.* On August 5, 2014, a CT of the chest, abdomen, and pelvis was clear of recurrent adenocarcinoma. *Id.* Subsequent scans performed in March 2015 and December 2015 were normal. *Id.* From January 2013, to May 2013, the Beneficiary was treated with bevacizumab and temozolomide. *Id.* Daily temozolomide treatments began in June 2013 and lasted until November 2013. *Id.* After November 2013, the

physician indicated that the Beneficiary again was lost to follow up. *Id.* The physician then noted that when the Beneficiary returned, his disease had progressed and the Beneficiary began Optune in May 2014. *Id.* According to the notes, the Beneficiary had clinical and radiographic response to the treatment. *Id.*

The physician reviewed the Beneficiary's serial MRI results. (Exh. 2, pp. 35-36). The images from July 23, 2014, and October 22, 2014, demonstrated "serially improved enhancing burden" in comparison to the image obtained on April 23, 2014, which was prior to Optune treatment. *Id.* The images obtained on February 15, 2015, May 17, 2015, October 22, 2015, February 16, 2016, and October 18, 2016, showed the Beneficiary's disease process was stable. *Id.* Imaging performed on February 16, 2017, showed the disease process had minimally evolved. *Id.* The physician indicated that the minimal radiographic changes seen did not warrant a change in treatment. *Id.* Strategies to maximize the Beneficiary's Optune compliance were discussed at the appointment. *Id.*

The report from the MRI performed on February 16, 2017, showed a small nodular focus of enhancement in the Beneficiary's left thalamus. (Exh. 2, p. 38). This area was not noted on prior imaging studies. *Id.*

An order prescribing Optune for the Beneficiary's treatment was completed on May 6, 2017, for a period of six months. (Exh. 2, p. 2). A second order was signed and completed on September 5, 2017, for continuation of therapy for an additional six months. (Exh. 2, p. 1).

Delivery documentation showed the Beneficiary received the Optune device and accessories on May 7, 2017. (Exh. 2, p. 19).

Also included in the record were multiple agreements between the Beneficiary and the Supplier. (Exh. 2, pp. 5-31). Although some of these agreements referenced an Advance Beneficiary Notice received by the Beneficiary, a copy of this notice was not found in the record.

Glioblastoma is a primary malignancy of the brain. (Exh 2, p. 141). With optimal treatment, the median survival of individuals diagnosed with glioblastoma is 15 months. *Id.* Standard treatment options include resection, chemotherapy, and radiation therapy. *Id.* Within nine months of initial treatment, most tumors recur. *Id.* Treatment options after recurrence are generally limited and include repeat resection with possible implantation of carmustine wafers, additional radiation therapy, and chemotherapy. *Id.*

Optune uses low-intensity electric fields to help slow or stop glioblastoma cancer cells from dividing.[1] Four adhesive patches, or transducer arrays, are applied to the scalp and connected to the device and a battery to deliver the therapy. *Id.* According to the Provider's instructions for the use of Optune, the treatment is intended for adult patients who are 22 years of age or older with histologically confirmed glioblastoma multiforme. (Exh. 2, p. 60). For adult patients with newly-diagnosed, supratentorial glioblastoma, Optune coupled with temozolomide is indicated following maximal debulking surgery and completion of radiation therapy along with standard of care chemotherapy. *Id.* Optune is indicated, according to the Provider's instructions, for the

[1] *See* https://www.optune.com/therapy/how-therapy-works.

treatment of recurrent glioblastoma following histologically or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. *Id.* For recurrent glioblastoma, Optune is intended to be used as a monotherapy and as an alternative to standard medical therapy for glioblastoma after surgical and radiation options have been exhausted. *Id.*

Optune, previously called NovoTTF-100A System, received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011.[2]

On October 5, 2015, the Supplier received premarket approval from the FDA for use of Optune in patients newly diagnosed with glioblastoma.[3]

In an article published in 2012 in Expert Reviews Neurotherapy, results of a phase III clinical trial for recurrent glioblastoma were discussed. *See* Fonkem E. and Wong E., NovoTTF-100A: a new treatment modality for recurrent glioblastoma, *Expert-Reviews* (2012); (Exh. 2, pp. 151-162). This article reported that TTFT "has comparable efficacy, and less toxicity, when compared to conventional drug treatments in the recurrence setting." *Id.* The results of this clinical trial led to the FDA premarket approval for the use of the NovoTTF-100A device as monotherapy for recurrent glioblastoma.

Interim results of a later clinical trial for newly diagnosed patients showed significant improvement in outcomes of the patients, leading to crossover of trial subjects from the control group to the experimental group. On December 15, 2015, the Journal of the American Medical Association ("JAMA") published an article analyzing the results of this phase III clinical trial related to TTFT.[4] The analysis of the clinical trial showed that adding TTFT to maintenance temozolomide in a population with new onset glioblastoma "significantly prolonged progression-free and overall survival." *Id.* After conclusion of the study, patients in the control group with ongoing maintenance therapy were offered TTFT therapy. *Id.* Thirty-five of those patients chose to receive TTFT therapy. *Id.*

The National Comprehensive Cancer Network ("NCCN") included alternating electric field therapy for glioblastoma in its NCCN Clinical Practice Guidelines in oncology Central Nervous System Cancers guidelines version 1.2016. (Exh. 2, pp. 43-46). Use of alternating electric field therapy for recurrent glioblastoma was given a 2B rating. *Id.*

At hearing, the Beneficiary's counsel explained the Beneficiary's medical history and progression of the glioblastoma. (Hearing testimony). In 2011, the Beneficiary was diagnosed with glioblastoma. *Id.* He underwent conventional treatments of surgery, radiation, and chemotherapy. His conventional therapy was ended in November 2013. *Id.* After multiple rounds of treatment, disease progression was found. *Id.* At that point, the Beneficiary had exhausted other treatment options and was not eligible for resection or chemotherapy. *Id.* The Beneficiary began using the Optune device in May 2014, after which the disease was shown to

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[2] http://www.accessdata.fda.gov/cdrh_docs/pdf10/p100034a.pdf.
[3] http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013a.pdf.
[4] Stupp, Roger, M.D. et al., *Maintenance Therapy With Tumor-Treating Field Plus Temozolomide vs Temozolomide Alone for Glioblastoma A Randomized Clinical Trial*, 314 JAMA 2535 (2015); (Exh. 3, pp. 1-8).

be stable. *Id.* No other treatment options were used after the Beneficiary began using Optune. *Id.* The Beneficiary continued using the Optune device through the dates of service. *Id.* For an individual diagnosed with recurrent glioblastoma, the prognosis is six months. *Id.* This Beneficiary has survived beyond that point. *Id.* After this treatment began, the Beneficiary's MRI showed no changes and the Beneficiary was clinically and radiographically stable. *Id.*

At times, patients using TTFT require a break from the therapy, which the Provider's representative stated was within the guidelines. *Id.* Patients at times can develop a rash or they are unable to tolerate the treatment every night. *Id.* It would be optimal for patient compliance to be 100%, but even with 30% compliance, clinical benefit can be seen. *Id.* Closer to 70% compliance, however, would be ideal. *Id.* This Beneficiary's success with the treatment showed compliance. *Id.*

The Optune device received FDA approval in April 2011 for use with recurrent glioblastoma. *Id.* The device exhibits minimal toxicity and provides patients with a better quality of life than other treatments. *Id.* Further, the NCCN guidelines include alternating electric field therapy for treatment of glioblastoma. *Id.* TTFT is prescribed in all fifty states, the District of Columbia, and Puerto Rico. *Id.* Finally, the Beneficiary's counsel explained that the LCD is under reconsideration at this time. *Id.*

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party that is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. 42 C.F.R. § 405.1014; Act § 1869(b)(1)(A). In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after the Appellant receives the QIC's reconsideration decision. The Appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the Appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. This ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* This ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. §§ 405.1000(g), .1038(a).

C. Standard of Review

The ALJ reviews and evaluates the evidence without regard to the findings made by the lower levels on the claim (*de novo* review). 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Sections 1814(a)(1), 1815(b), and 1833(e) of the Act; 42 C.F.R. § 424.5(a)(6), 42 C.F.R. §§ 405.1018, .1028, .1030.

II. Principles of Law

A. *Statutes & Regulations*

The statutory authority for the Medicare program is found in Title XVIII of the Act. *See* 42 U.S.C. § 1395 *et. seq.* The Supplementary Medical Insurance program (Part B of Title XVIII of the Act) provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. *See* Act § 1832; *see also* 42 C.F.R. § 410.10. The Secretary of HHS has authority to promulgate regulations which define or clarify the provisions of the Act. Those regulations are generally found at 42 C.F.R. § 410, and other provisions.

Notwithstanding any other provision of Title XVIII, "no payment may be made under part A or part B for any expenses incurred for items or services-which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Act § 1862(a)(1). Custodial care expenses are also excluded from Medicare Coverage. Act § 1862(a)(9); 42 C.F.R. § 411.15(g), (k).

The Act provides that Medicare part B pays for the rental or purchase of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") if the equipment is used in the patient's home or in an institution that is used as a home. *See, e.g.*, Act §§ 1832(a)(1), (a)(2)(B), (a)(2)(I), 1834(a)(13), 1861(s)(6); 42 C.F.R. § 410.3. *See also* Act § 1861(n) (defining "durable medical equipment").

> Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:
> (1) Can withstand repeated use.
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.
(4) Generally is not useful to an individual in the absence of an illness or injury.
(5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

> Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:
> - The equipment meets the definition of DME (§110.1);
> - The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
> - The equipment is used in the patient's home.

CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-02)* ch. 15, § 110 (Oct. 2016).

In the event the services are found to be "not medically reasonable and necessary," or "custodial in nature," under § 1862(a)(1) or (9) of the Act, § 1879 of the Act provides for limitation on liability for Medicare payments. If the beneficiary had no knowledge that the services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. § 411.400 *et seq.* and HCFA Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under § 1879 of the Act. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. 42 C.F.R. § 411.406.

B. Policy and Guidance

ALJ's must give the manuals and rulings substantial deference. 42 C.F.R. § 405.1062(a). Unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. Act § 1871(a)(2); 42 C.F.R. § 405.1060. However, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations ("LCDs"). The applicable provisions in the LCDs and Medicare manuals are entitled to substantial deference to the extent they are consistent with the Act, regulations, and rulings; deviation from them must be explained. 42 C.F.R. § 405.1062. All relevant LCDs and Medicare manuals are hereby given substantial deference. The authority to promulgate manuals and other policy issuances is found, in part, in Section 1842 of the Act.

A Noridian Administrative Services Local Coverage Determination, LCD L34823, Tumor Treatment Field Therapy is relevant for this case. This LCD provides that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. Noridian Healthcare Solutions, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (LCD L34823) (Jan. 2017). The related Policy Article states that tumor treatment field therapy devices are

covered under the Durable Medical Equipment benefit and must meet the reasonable and necessary requirements set out in the related LCD to be eligible for reimbursement. Noridian Healthcare Solutions, LLC, Local Coverage Article for Tumor Treatment Field Therapy Article A52711 (Article A52711) (Jan. 2017). The code E0766 is used to describe devices that generate electromagnetic fields utilized in the treatment of cancer. *Id.* This code is inclusive of all associated supplies. *Id.*

According to guidance contained in the Medicare Benefit Policy Manual, even though an item may be classified as DME, it may not be covered in every instance. In particular cases, coverage is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. MBPM ch. 15, § 110.1.C. Additional factors to be considered are the necessity of the equipment, the reasonableness of the equipment, whether payment is consistent with what is necessary and reasonable, and establishing the period of medical necessity.

The Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM), ch. 13 § 13.5.1, and the Medicare Benefit Policy Manual (CMS Pub. 100-02) (MBPM), ch. 15 § 110, provide guidance for determining whether a device is reasonable and necessary. These manuals suggest that a device is reasonable and necessary if it is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the item in terms of whether it is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the patient's medical needs and condition;
    - Ordered and furnished by qualified personnel;
    - One that meets, but does not exceed, the patient's medical need; and
    - At least as beneficial as an existing and available medically appropriate alternative.

MPIM, ch. 13, § 13.5.1.

Medicare also instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either "published authoritative evidence" such as "definitive randomized clinical trials" or "general acceptance by the medical community," with the caveat that "[a]cceptance by individual health care providers" and "limited case studies distributed by sponsors with a financial interest in the outcome[] are not sufficient evidence of general acceptance by the medical community." MPIM § 13.7.1.

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. *MBPM* ch. 15, § 110.1.C. In terms of reasonableness, even though an item of DME may serve a useful medical purpose, the Contractor must also consider what extent it would be reasonable for the Medicare program to pay for the item prescribed. The following are considerations in determining reasonableness:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

Id.

Finally, the MPIM states that LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to **convincingly refute** evidence presented in support of coverage. *MPIM, supra* ch. 13, § 13.7.1. (emphasis added). However, "less stringent evidence is needed when allowing for individual consideration." *Id.*

Analysis

This Administrative Law Judge conducted a *de novo* review of the evidence to determine whether the Appellant established the requirements for Medicare coverage. Appellant's request for an ALJ hearing was timely and satisfied jurisdictional requirements. In this case, this ALJ finds and concludes that the tumor treatment field therapy for treatment of this Beneficiary's glioblastoma for the dates of service was medically reasonable and necessary.

First, this ALJ notes that there is no National Coverage Determination specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.*

In this case, this ALJ declines to follow LCD L34823 because this ALJ finds that the device is categorized as an item of durable medical equipment, which is a Medicare-covered benefit category; tumor treatment field therapy is medically reasonable and necessary to treat this Beneficiary's condition; and no alternative treatment modalities were available to this Beneficiary.

I. Medicare-Covered Benefit Category

The Policy Article categorically places the TTFT device in the durable medical equipment category of Medicare-covered benefits. According to the relevant Policy Article, "tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act § 1861(s)(6))." Article A52711. In fact, the Contractor provided the associated HCPCS code for the equipment and reported that the code, E0766, was in the frequent and substantial servicing payment category. Given the Contractor's clear acceptance of the TTFT devices as items of durable medical equipment that are covered under the Medicare durable medical equipment benefit, further analysis of this issue is not necessary.

II. The TTFT is Medically Reasonable and Necessary

According to the Medicare Program Integrity Manual, contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative.

MPIM ch. 13, § 13.5.1.

A. Safe and Effective Therapy

Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Act § 1862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental.

First, this ALJ finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. The FDA website explains that premarket approval ("PMA") entails the following:

> PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).[5]

While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use in patients with both recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven

[5]http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm

safe and effective based on authoritative evidence. The Contractor, however, looked to the FDA panel debate regarding the device to question the safety and effectiveness of TTFT.

In June 2014, the Contractor published responses to comments it received regarding TTFT. DME Happenings, Noridian DME Jurisdiction D, June 2014, Issue No. 43. In regard to the FDA approval of TTFT, the Contractor stated that while the FDA did approve the application with a positive vote of the FDA's Medical Device Advisory Committee's Neurological Devices Panel, the decision was split with six yes and six no on the question of whether the device was effective for use. *Id.* This vote was then decided by a tie-breaker vote cast by the panel chairperson. *Id.* While this is true, this information regarding the debate of the panel does not negate the fact that the end result of the vote was that the FDA approved the use of the device as safe and effective.

Second, this ALJ has reviewed clinical studies related to the use of the Optune device which have also concluded that the device is safe and effective. Results from a phase III clinical trial utilizing TTFT in patients with recurrent glioblastoma was shown to have equivalent efficacy when compared to the best physician's choice for chemotherapy. (Exh. 2, pp. 140-150). It is important to note that within the clinical trial, no limit was placed on the number or type of prior therapies or recurrences for the participants. *Id.* Uninterrupted treatment was recommended for the study, but breaks were permitted of up to one hour twice a day for personal care and participants were permitted to take two to three days off treatment at the end of every four weeks of treatment. *Id.* Findings from the study showed that TTFT demonstrated a "non-significant increased response rate…a trend towards reduction of the risk of death…as well as sustained improvement in [quality of life]." *Id.* Overall, TTFT was found to be at least equivalent to active chemotherapy. *Id.* However, the quality of life associated with TTFT was better than those receiving active control chemotherapy. *Id.* For instance, more gastrointestinal, hematological, and infectious events were noted in the chemotherapy group. *Id.*

With respect to patients newly diagnosed with glioblastoma, results of a phase III study released in a December 15, 2015, JAMA article showed that adding TTFT to maintenance temozolomide significantly prolonged progression-free and overall survival. (Exh. 2, pp. 48-57). Significantly, patients in the control group in the JAMA-reported study crossed over to the combined therapy group for TTFT treatment due to the improvement in outcomes seen. *Id.*

Specifically for the treatment of this Beneficiary's recurrent glioblastoma, the FDA approval and the clinical trials showed that the Optune device was safe and effective.

B. Not Experimental or Investigational

The use of TTFT is generally accepted by the medical community. In the 2016 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option categorized as 2B for glioblastoma. (Exh. 2, pp. 43-46). This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. As such, this ALJ finds that TTFT treatment is accepted in the medical community as safe and effective for the treatment of recurrent glioblastoma.

In its June 2014 response to comments on TTFT, the Contractor also addressed the NCCN guidelines. DME Happenings, Noridian DME Jurisdiction D, June 2014, Issue No. 43. Commenters suggested that NCCN category 2B showed TTFT should be covered as standard of care. The Contractor responded that NCCN category 2B means that based on "lower-level evidence, there is NCCN consensus that the intervention is appropriate." *Id.* Category 2A means "uniform NCCN consensus that the intervention is appropriate." *Id.* While CMS did not address NCCN guidelines as they relate to medical devices for the treatment of cancer, the Contractor referenced the Medicare Benefit Policy Manual guidance regarding NCCN evidence for off-label use of drugs and biologicals in treating cancer. *Id.* Under this MBPM guidance, the use of the drug would qualify as a medically accepted indication if the indication is a Category 1 or 2A in the NCCN. *Id.* Whereas a Category 3 indication in the NCCN would not qualify as a medically accepted indication. *Id.*

This ALJ, however, finds that referencing the MBPM guidance regarding off-label use of drugs and biologicals does not correspond to using a medical device as approved by the FDA. If a drug is being used as approved by the FDA, it is not necessary to look to Medicare-approved compendia regarding off-label uses to further determine whether the use is appropriate. Off-label, as the name suggests, indicates that the specific use contemplated was not approved by the FDA. Here, the FDA approved the use of TTFT for recurrent glioblastoma as safe and effective. Further, the MBPM did not specifically address a category 2B classification by the NCCN. The NCCN category 2B definition suggests a 2B category showed lower-level consensus that the intervention is appropriate. Generally-accepted does not mean uniformly accepted, but instead something less stringent. Here, this ALJ accepts the category 2B consensus as appropriate for this Beneficiary, particularly in light of his normally terminal diagnosis and lack of alternative treatments.

Overall, a review of the literature available showed that the Optune device received FDA premarket approval, showing that it was safe and effective and not experimental; the use of the Optune device in a population with recurrent glioblastoma was proven effective and appropriate through a phase III clinical trial; and the use of the Optune device appears in national cancer treatment guidelines for treatment of glioblastoma, showing general acceptance by the medical community.

C. The Use is Appropriate for this Beneficiary

The final question addressed in the *MPIM* is whether the item is appropriate, which the manual breaks down into multiple questions.

Here, the item was furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition. This Beneficiary had recurrent, supratentorial glioblastoma multiforme. The FDA approved the use of the Optune device in adult patients with histologically-confirmed glioblastoma multiforme, following histologically- or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device was approved as a monotherapy and was intended as an alternative to standard therapy after surgical and radiation options were exhausted. As previously discussed, the Beneficiary

had exhausted all conventional therapy options, including surgery, radiation, and chemotherapy, and was using the Optune device as monotherapy for the treatment of supratentorial glioblastoma.

The device also generally is a portable device used in the patient's home or other settings, which are appropriate for this Beneficiary's medical needs and condition. The device was ordered by the Beneficiary's treating physician and the device meets, but does not exceed, the Beneficiary's medical needs. Finally, the device is at least as effective as existing and available medically appropriate alternatives. Considering that the Beneficiary had exhausted all appropriate alternative, conventional therapies, the Optune device would certainly meet this aspect of the medically reasonable and necessary considerations.

One final aspect that must be considered is whether this device is substantially more costly than a medically appropriate and realistically feasible alternative pattern of care. In a notice of intent to publish a proposed rule and soliciting comments for criteria used to make local coverage decisions, the Health Care Financing Administration (HCFA), the precursor to the Centers for Medicare and Medicaid Services, stated that it was important for the Medicare program to be responsive to the rapid advances in health care. 65 Fed. Reg. 31124, 31125 (May 16, 2000). This HCFA request for comments added that two criteria would likely be applied when making an NCD or LCD: 1. The item or service must demonstrate medical benefit, and 2. The item or service must demonstrate added value to the Medicare population. *Id.* An item was defined to be medically beneficial if it produced a "health outcome better than the natural course of illness or disease with customary medical management of symptoms." *Id.* In addition, "quality of life" was an acceptable health outcome named in the proposal. *Id.* One example provided in the notice as demonstrating added value was "when a new item or service that falls within a Medicare benefit category would be medically beneficial for a beneficiary with a given clinical circumstance and there is no Medicare-covered medically beneficial alternative." *Id.* This item or service "would add value to the program and we should cover it without consideration of costs during the coverage process." *Id.* However, for clinically substitutable services "it is not reasonable or necessary to pay for incurred costs that exceed the cost of a Medicare-covered alternative that produces the same health outcome." *Id.* Finally, if an equivalent service is "substantially more expensive than a Medicare-covered alternative" then cost considerations would lead to denial of coverage for the services. *Id.*

As reflected in the record, this Beneficiary had exhausted the conventional, alternative treatment modalities for recurrent glioblastoma. On November 28, 2011, the Beneficiary underwent resection of the tumor. (Exh. 2, p. 35). When surrounding heterogeneous enhancement was noted on MRI, resection was deferred because of callosal involvement. The Beneficiary had gone through temozolomide chemoradiation, which was complicated by generalized seizure. *Id.* He also underwent bevacizumab chemotherapy from January 2013, to May 2013, temozolomide therapy on a monthly basis from January 2013, to May 2013, and temozolomide therapy on a daily basis from June 2013, to November 2013. *Id.* Despite this treatment, the Beneficiary's disease progressed. In May 2014, after the Beneficiary had exhausted alternative treatment modalities, the Beneficiary started the use of the Optune device as monotherapy. *Id.* Since that time to the dates of service, the Beneficiary continued the use of the device. (Hearing testimony).

A review of the medical records and hearing demonstrated that this Beneficiary had already undergone surgical resection of the tumor, chemoradiation, and postradiation chemotherapy. When he began treatment with the Optune device, the Beneficiary had exhausted other treatment options and his disease continued to progress. This Beneficiary had no feasible Medicare-covered alternative pattern of care available to halt the progression of his disease. After beginning treatment, the Beneficiary's disease progression stopped, which prolonged the lifespan of the Beneficiary well beyond the general prognosis of six months for recurrent glioblastoma. The cost of this device, while high, does not outweigh the personal experience and needs of this Enrollee with respect to the TTFT device.

For the reasons stated above, this ALJ finds that Optune (TTFT) has been shown to be safe and effective and is medically reasonable and necessary for the treatment of this Enrollee's condition.

Conclusions of Law

This decision is **FULLY FAVORABLE** for the Appellant. This Administrative Law Judge decides that the Optune device using tumor treatment field therapy was medically reasonable and necessary for the treatment of the Enrollee's glioblastoma for the dates of service of August 7, 2017, September 7, 2017, and October 7, 2017.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: NOV 0 8 2018

David Krane
U.S. Administrative Law Judge

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

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NOTICE OF DECISION

Appellant: R. Townsend
OMHA Appeal Number: 1-8116629727

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod.**

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

Novocure, Inc.
195 Commerce Way
Portsmouth, NH 03801

R. Townsend
750 Grand Concourse, #4L
Bronx, NY 10451

Enclosures:

OMHA-152, Decision
DAB-101, Request for Review

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio

Appeal of: **R. Townsend**	ALJ Appeal No.: **1-8116629727**
Beneficiary: **R. Townsend**	**Medicare Part B**
HICN: *******3358A**	Before: **Thomas S. Tyler** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** on-the-record decision is entered for the Beneficiary.

Procedural History

Novocure, Inc., the provider, submitted claims to Medicare for tumor treatment field therapy (TTFT), electric stimulation ("Optune") cancer treatment (E0766) it provided to the Beneficiary from February 7, 2018 to April 7, 2018. The claims were denied initially and upon reconsideration. The matter was then forwarded to C2C Solutions, Inc., a qualified independent contractor (QIC), which issued an unfavorable decision on November 15, 2018 and found the provider liable for payment of the non-covered services.

The Office of Medicare Hearings and Appeals (OMHA) received the Appellant's timely filed appeal. The remaining amount in controversy meets the jurisdictional requirements for a hearing before OMHA.

A telephone hearing in this matter was scheduled to be held on January 28, 2019 at 2:30 PM EST in Cleveland, Ohio before the undersigned ALJ. However, because all of the issues have been resolved in the Beneficiary's favor, a hearing was not conducted and a decision on-the-record has been entered. All exhibits were entered into the record.

Issue

The issue is whether the tumor treatment field therapy (TTFT) provided to the Beneficiary from February 7, 2018 to April 7, 2018 is covered under Medicare Part B.

Findings of Fact

The Beneficiary in this case is a 54 year-old man who was diagnosed with glioblastoma (GBM) in November 2014. His physician prescribed chemotherapy, radiation and surgery to treat his GBM. The physician described the GBM as "refractory to chemotherapy, bevacizumab, radiation and surgery." (Exhibit 2, p. 10). The Beneficiary initially signed for what was previously known as the NovoTTF-100A System on April 30, 2014. (Exhibit 2, p. 14). The same system is now known in short as Optune. Optune is durable medical equipment that delivers alternating electric fields or tumor treating fields to the brain. The device consists of an electric field generator which is connected to four insulated transducer arrays. The arrays are placed on the patients scalp deliver the tumor treating fields in order to interfere with the tumors' abilities to regenerate. (Exhibit 1).

On September 5, 2017 and February 19, 2018, the Beneficiary's physician again prescribed the Optune system (E0766). (Exhibit 2, p. 12-13; Beneficiary's Pre-hearing Brief). The Beneficiary's oncologist stated that GBM is the most aggressive primary brain tumor that nearly universally recurs despite multimodality treatment of surgery, radiation and chemotherapy. (Exhibit 2, p. 10). It is considered an "orphan disease" because of its rarity and the lack of treatment options. (*Id.*).

The record contains multiple articles from studies that favorably recommend the treatment of glioblastoma with the Optune therapy. (Exhibit 1).

Ms. Parrish, the Beneficiary's legal counsel, maintains that Optune is the standard of care for treatment of either newly discovered or recurring GBM. Further, she notes that Optune has been accepted by the FDA and is included in the National Comprehensive Cancer Network guidelines as an appropriate method of treatment of recurrent and newly diagnosed GBM.

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is $160 or more. *See* 76 Fed. Reg. 59138 (Sept. 23, 2011) and 42 C.F.R. §405.1006(b)(2). The request for

hearing is timely if filed within sixty days from the date the party receives notice of the QIC's reconsideration. *See* 42 C.F.R. § 405.1014(b)(1).

B. Scope of Review

Under the implementation policy of the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services, all appeal requests stemming from a QIC reconsideration are governed by the Administrative Law Judge Hearing Procedures outlined in 42 C.F.R. §§ 405.1000 – 1018. 70 Fed. Reg. 11425 (March 8, 2005).

The issues before the administrative law judge include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the party's favor. However, if evidence presented before the hearing causes the administrative law judge to question a favorable portion of the determination, the administrative law judge will notify the parties before the hearing and may consider it an issue at the hearing. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The Office of Medicare Hearings and Appeals is staffed with Administrative Law Judges who conduct de novo hearings. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Title XVIII of the Social Security Act (the Act), is administered through the Centers for Medicare and Medicaid Services (CMS), a component of the United States Department of Health and Human Services (HHS). Under the authority of Section 1842(a) (1) (A) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program.

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

Sections 1832(a)(2)(B), 1861(s)6), and 1862(a)(1)(A) of the Act provide that Part B covers durable medical equipment (DME) that is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII, § 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Title XVIII, § 1861 of the Act addresses prosthetic devices as follows:

> (s) The term "medical and other health services" means any of the following items or services:
>
> (8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;
> (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition.

B. Medicare Manual System

Administrative Law Judges may also give consideration to the manuals and rulings issued by the CMS in determining benefit coverage and eligibility. Although not binding on the Administrative Law Judge, the respective manuals provide guidance in the administration of the Medicare program. (*Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995)).

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS. However, although not subject to the force and effect of the law, CMS and its contractors, have issued policy and guidelines, including Local Coverage Determinations (LCD's) that describe criteria for coverage for selected types of medical services and supplies. NCDs promulgated by the Secretary of HHS under the authority of § 1862(a)(1) of the Act dictate the criteria under which specified services, procedures or supplies are covered by Medicare. NCDs are binding upon ALJs. 42 CFR §405.732(a)(4). "An ALJ may not disregard, set aside or otherwise review an NCD." (42 CFR §405.732(b)(1)).

There is no NCD specific to tumor treatment field therapy. However, there is a local coverage determination that can be found at L34823. Local Coverage Determination, L34823 addresses tumor treatment field therapy (TTFT). It states:

> For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
>
> For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an

item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

A4555 ELECTRODE/TRANSDUCER FOR USE WITH ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, REPLACEMENT ONLY

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

However, policy article A52711 provides that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.

Analysis

At issue in this case is whether reimbursement can be made for the TTFT therapy provided to the Beneficiary from February 7, 2018 to April 7, 2018.

The Local Coverage Determination that addresses TTField therapy, L34823, specifically denies coverage. It states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. The LCD does not provide any circumstances under which TTField therapy would be covered.

The Beneficiary in this case has glioblastoma and was given a prescription by his treating physician to use both TTField therapy and concurrent chemotherapy and radiation. The Beneficiary stated that he understands that there is an LCD that states that TTField therapy is not medically reasonable and necessary but noted that the last revision of the LCD L34832 was in 2013. The Beneficiary explained that the Optune therapy system that is at issue in this case was FDA approved for treatment of glioblastoma.

While we acknowledge that Medicare appropriately considered LCD L34832 in making the decision to deny the TTField therapy in this case based upon the unambiguous pronouncement that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary," we decline to follow that statement in the LCD. The Code of Federal Regulations identify the applicability of Local Coverage Determinations. It states that LCDs are required to be adhered

to by Medicare contractors. (42 C.F.R. §405.1062). However, Administrative Law Judges and the Medicare Appeals Council are not bound by LCDs. If an ALJ declines to follow an LCD in a particular case, he or she may do so, but must explain why the policy was not followed. (*Id.*).

LCD L34832 does specifically state that TTField therapy will be denied as not reasonable and necessary. The tumor treatment field therapy that the Appellant is seeking is called "Optune." "Optune is a portable battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields (TTFields) within the human body. The TTFields are applied to the patient's shaved head by means of electrically insulated surface transducer arrays, such that resistively coupled electric currents are delivered to the patient. The TTFields disrupt the rapid cell division exhibited by cancer cells." https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf. While we acknowledge that the Plan and QIC appropriately considered LCD L34823 in making the decision to deny the Optune treatment in this case based upon the unambiguous pronouncement that the type of treatment is not reasonable and necessary, we decline to follow that statement in the LCD. No explanation was provided by the LCD for the failure to cover the TTField therapy. Certainly, the LCD is not required to include reasons for the denial of non-covered services. However, in giving an LCD its required deference when considering whether to abide by a pronouncement that is not binding on an ALJ, the reason for the non-coverage would be helpful to assess the applicability of the LCD. Here, we cannot determine the reasons for non-coverage but find that the rationales for coverage are extensive. In exercising our review authority, we do not follow the LCD and offer this Decision in explanation. (42 C.F.R. §405.1062(a)).

Without an explanation in the LCD as to why TTF therapy is considered as not medically reasonable and necessary, we are left to speculate. The TTFT was likely an emerging technology that had not been widely reviewed or tested for medical efficacy at the time the language was included in the LCD limiting its coverage. However, Optune was approved by the FDA for use in the treatment of newly diagnosed glioblastoma on October 5, 2015[1]. Moreover, at around the same time of the last LCD update, there were studies conducted and the results published passing on the efficacy of the use of TTField therapy, most notably the Optune (NovoTTF-100A therapy), for recurrent and new diagnoses of glioblastoma. *Stupp et al., NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomized phase III trial of a novel treatment modality*. Eur J Cancer. 2012 Sep; 48(14):2192-202. The results of further studies were presented in the Annual Meeting of the American Association for Cancer Research. *Stupp, Hegi, Ibdaih, et al. Tumor treating fields added to standard chemotherapy in newly diagnosed gliobastoma (GBM): final results of a randomized, multicenter phase III trial*, Program and Abstracts of the 2017 Annual Meeting of the American Association for Cancer Research April 1-April 5, 2017 Washington, D.C. Abstract LBA AACR CT007. The results of these studies determined that Optune in combination with temozolomide was an effective treatment of this particular brain cancer, whether newly diagnosed or recurrent, that resulted in significant improvement in life expectancy of most patients.

We are also persuaded by the Beneficiary's medical provider. The Beneficiary's physician prescribed the treatment at issue in this case and credibly explained in a letter in the file that the

[1] https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf

treatment had excellent results for others with the Beneficiary's disease and noted that there are few other promising treatment options. (Exhibit 2, p. 10-11).

On the basis of the foregoing, we decline to follow the LCD. The FDA approval of Optune, the overwhelming medical research evidence and the written statement by the Beneficiary's physician discloses that Optune is effective in extending the lives of patients who have been newly diagnosed or have recurrent glioblastoma. We do not fault the Medicare contractors for coming to a different conclusion. They adhered to the pronouncement in the LCD. However, if ever there was a reason for an ALJ to vary from the strict, unexplained pronouncement in an LCD, it is this case where the very life of the Beneficiary holds in the balance, with very few, if any, other medical options to treat him and prolong his life aside from the treatment provided by the Optune device.

Consequently, the undersigned finds that the Medicare requirements have been met. Accordingly, the ALJ finds that the TTFT treatment provided to the Beneficiary in this case are covered under Medicare Part B.

Conclusions of Law

Based on the foregoing, the undersigned concludes as a matter of law that the Optune Tumor Treatment Field Therapy services were shown to be medically reasonable and necessary and are covered under Medicare. The Beneficiary is entitled to reimbursement of all the items as billed.

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

Dated: 2/4/19

Thomas S. Tyler
U.S. Administrative Law Judge

 19-113

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Cleveland Field Office
200 Public Square, Suite 1300
Cleveland, OH 44114-2316
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216-615-7534 (ALJ Butler Team)
216-615-7130 (Fax)
866-236-5089 (Toll Free)

Date: June 25, 2019

DEBRA M PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: R. TOWNSEND
OMHA Appeal Number: 1-8429561876

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

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Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

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Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

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decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

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The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

R. TOWNSEND
750 GRAND CONCOURSE APT 4L
BRONX, NY 10451-3118

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

NOVOCURE INC.
195 Commerce Way
Portsmouth, NH 03801

Enclosures:

OMHA-152, Decision
DAB-101, Request for Review

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____ . I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland, Ohio

Appeal of:	**R. TOWNSEND**	OMHA Appeal No.:	**1-8429561876**
Beneficiary:	**R. TOWNSEND**	Medicare:	**Part B**
Medicare No.:	*****3358A**	Before:	**Brian J. Butler** Administrative Law Judge

DECISION

After carefully considering the evidence, arguments and testimony presented in the record, this decision is **UNFAVORABLE** to the Appellant, R. Townsend.

Procedural History

The Appellant received treatment with a tumor treatment field therapy (TTFT) device called Optune which was supplied by Novocure, Inc. (Supplier). Claims were submitted to Medicare for dates of service on August 7, 2018, September 7, 2018, and October 7, 2018. On August 13, 2018, September 13, 2018, and October 13, 2018, Medicare through Contractor Noridian Healthcare Solutions, denied payment of the claims. (Ex. 1, p. 22). On January 3, 2019, Noridian issued a redetermination affirming the initial denial of the claims. (Ex. 1, p. 21).

The Appellant requested reconsideration. (Ex. 1, p. 16). On March 19, 2019, the Qualified Independent Contractor (QIC), C2C Innovative Solutions, Inc., determined the device was not covered under Medicare. The QIC found the Supplier liable for the non-covered claims. (Ex. 1, p. 1).

On April 1, 2019, the Appellant timely filed a request for an Administrative Law Judge (ALJ) hearing. (Ex. 3, p. 1). The amount in controversy satisfies the jurisdictional requirements for an Administrative Law Judge (ALJ) hearing before the Office of Medicare Hearings and Appeals. The Appellant was represented by Attorney Debra Parrish pursuant to a valid Appointment of Representative. (Ex. 3, p. 4). A hearing was held on May 29, 2019. (Ex. 4, p. 1). Attorney Bridget Noonan, an attorney with Attorney Parrish's firm, appeared on behalf of the Appellant who chose not to participate in the hearing. Timothy Parks, Clinical Appeals Specialist for Novacure, were present for the Supplier. All Exhibits were entered into the record without objection.

Issue

The issue is whether use of the TTFT for dates of service August 7, 2018, September 7, 2018, and October 7, 2018 to assist with the treatment/management of the Appellant's glioblastoma is covered under Medicare Part B, and, if not, who is liable for payment.

Findings of Fact

The Appellant, a 54-year old male, reported headaches in 2011. He was diagnosed with glioblastoma multiforme (GBM) that was surgically resected on November 28, 2011. Temozolomide chemoradiation was complicated by general seizures. He presented to the hospital in December, 2012 with progressive left-sided weakness and confusion. MRI revealed a right frontal resection cavity with surrounding heterogeneous enhancement, but resection was deferred for callosal involvement. The Appellant then developed colon cancer in May, 2013. He was treated with Bevacizumab from January through May, 2013 and Temozolomide from January through November, 2013. He had disease progression and started Optune in May, 2014. (Ex. 2, p. 65).

After starting Optune, repeat MRIs throughout 2015-2018 were stable. The office visit note from March 22, 2018 states the diagnosis was recurrent GBM. Strategies were reviewed to maximize Optune compliance. (Ex. 2, p. 54).

In April 2011, the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) approved commercial distribution of the Optune device for treatment of adult patients (22 years of age and older) with histologically-confirmed glioblastoma multiforme (GBM) following histologically- or radiologically- confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. In the pre-market approval letter, CDRH noted the device was intended to be used as a monotherapy, and was intended as an alternative to standard medical therapy for GBM after surgical and radiation options had been exhausted. (Ex. 2, pp. 34-38).

In October 2015, the CDRH issued a pre-market approval supplement for Optune. The supplement approved Optune as a treatment for adult patients (22 years of age or older) with histologically-confirmed GBM and Optune with temozolomide for the treatment of adult patients with newly diagnosed, supranentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant chemotherapy. (Ex. 2, pp. 39-42).

In 2018, the National Comprehensive Cancer Network (NCCN) Guidelines (version 1.2018; March 20, 2018) were updated to include alternating electric field therapy (TTFT) as an NCCN category I recommendation following post-operative standard brain radiation therapy with concurrent temozolomide. (Ex. 2, p. 28).

An affidavit was submitted from Justin Kelly, R.N., B.S.N. and Regional Vice President of Health Policy for Novocure stating that Optune is FDA approved. More than 800 oncology centers have been certified to provide and prescribe Optune. It has been prescribed by more than 1,200 providers for more than 7,200 patients. Its clinical effectiveness has been described in over 140 peer-reviewed publications. The device is accepted by the clinical community as treatment to improve the clinical outcomes and survival of patients with glioblastoma. (Ex. 2, p. 4).

By letter dated August 7, 2018, the DME-MAC Medical Directors for Noridian Healthcare Solutions and CGS Administrators confirmed receipt of the Provider's request for formal reconsideration of the TTFT Local Coverage Determination (LCD) coverage criteria. The letter notes that LCD L34823 only addresses coverage criteria of TTFT for recurrent GBM, and not newly diagnosed GBM. The DME-MACs accepted the Provider's request to add coverage guidance for newly diagnosed GBM. (Ex. 4, pp. 16-17, *Hearing Record*).

Peer-reviewed literature suggests that tumor-treating fields, also known as alternating electric fields, disrupt the cell division process in cancerous tumors which may lead to programmed cell death, or apoptosis. Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in GBM brain tumors compared with traditional standards of care alone. (Ex. 2).

A large number of health care insurance providers have medical policies in place allowing coverage for Optune for the treatment of glioblastoma multiforme when certain conditions are met. These providers include, but are not limited to AETNA, Highmark, Anthem, Humana, Kaiser, United Healthcare, Cigna, Geisinger, and Blue Cross Blue Shield. (See Ex. 2.).

Legal Framework

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is $140 or more. 42 C.F.R. § 405.1006. The request for hearing is timely if filed within sixty days after receipt of a QIC decision. 42 C.F.R. § 405.1014(b)(1).

B. Scope of Review

"The issues before the ALJ include all the issues brought out in the initial determination, redetermination or reconsideration that were not decided entirely in [the Appellant's] favor. However, if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, he or she notifies [the Appellant] before the hearing and may consider it an issue at the hearing." 42 C.F.R. § 405.1032(a).

C. Standard of Review

"The [Office of Medicare Hearings and Appeals]…is staff[ed] with Administrative Law Judges who conduct 'de novo' hearings…." 70 Fed. Reg. 36386 (June 23, 2005).

II. Principles of Law

A. Statutes and Regulations

Eligibility for Medicare benefits is determined under Title XVIII of the Act, 42 U.S.C. § 1801 et seq., and federal regulations set forth in Title 42 of the Code of Federal Regulations.

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term which is defined as including durable medical equipment. § 1861(s)(6) of the Act.

According to section 1862(a)(l)(A) of the Act, no payment may be made under Original Medicare for any expenses incurred for items or services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." See 42 U.S.C. § 1395y(a)(l)(A); see also 42 C.F.R. § 41 l.15(k)(l).

In the event the services are found to be "not medically reasonable and necessary (1862(a)(1))," or "custodial in nature (1862(a)(9))," Section 1879 of the Act provides for waiver of liability of Medicare payments. Section 1879 applies only to a denial by reason of "not medically reasonable and necessary" or "care was custodial in nature," and when:

(1) The item or service was furnished under assignment; and

(2) Neither the beneficiary, nor the provider/supplier knew or reasonably could have been expected to know that such services would be excluded from Medicare coverage.

42 C.F.R. § 411.406 imputes knowledge to a provider that services will not be covered based on information distributed by CMS. A provider should know services will not be covered based on CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs.

B. Policy and Guidance

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a national coverage determination (NCD), can establish or change a substantive legal standard governing the scope of the benefits or payment for services under the Medicare program unless promulgated as a regulation by CMS. NCDs promulgated by the Secretary of HHS under the authority of Section 1862(a)(l) of the Act dictate the criteria under which Medicare covers specified services, procedures or supplies. NCDs are binding upon ALJs. 42 C.F.R. § 405.1060(a)(4); see 42 C.F.R. § 405.1060(b)(l) ("An ALJ may not disregard, set aside or otherwise review an NCD").

Although not subject to the force and effect of law, CMS and its contractors issue policies, manuals and guidelines that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations (LCDs). 42 C.F.R. § 405.1062 states that an ALJ is not bound by LCDs or CMS program guidance, such as program

memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. An ALJ decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

LCD L34823 entitled "Tumor Treatment Field Therapy (TTFT)" provides that TTFT (E0766) will be denied as not reasonable and necessary.

Medicare Policy Article A52711 provides additional guidance for TTFT, and seems to provide some inconsistent analysis with the LCD, which purports to allow coverage where appropriate and states, as follows:

> **NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:**
>
> For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.
>
> Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(l)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.
>
> Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.
>
> Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

Analysis

The Appellant seeks coverage for TTFT under Medicare Part B for dates of service on August 7, 2018, September 7, 2018, and October 7, 2018. The Contractor denied the request which was subsequently upheld on appeal by the QIC. Having carefully considered the entirety of the administrative record, I conclude that Medicare Part B cannot be required to cover TTFT in this case.

The applicable Local Coverage Determination, LCD L34823, categorically denies coverage for TTFT as "not reasonable and necessary." While I am not bound by Local Coverage

Determinations, I must give substantial deference to these policies, unless there is a reason particular to the specific case that justifies deviation from such policy. See § 1852(a)(1) of the Act; and 42 C.F.R. § 405.1062. I am unable to find unique circumstances in this case that warrant deviation from the LCD which excludes coverage for TTFT.

The Appellant has, throughout the appeals process, essentially challenged the LCD noting that there is sufficient medical literature and broad acceptance in the medical community to conclude TTFT is reasonable and necessary for treatment of glioblastoma. For instance, the Appellant has noted TTFT has received pre-market approval from the FDA for recurrent glioblastoma in April 2011. Additionally, in 2015, TTFT received pre-market approval from the FDA for newly diagnosed glioblastoma in combination with temozolomide after standard surgical resection and radiation therapy. In addition to FDA approval, the Appellant cited to numerous research articles showing TTFT, in combination with temozolomide, is an effective treatment of glioblastoma, whether newly diagnosed or recurrent, and resulting in significant improvement in life expectancy for most patients.

Furthermore, an affidavit signed by the Supplier's Vice President indicates TTFT has been deemed clinically safe and effective for treatment of glioblastoma noting the treatment is covered by many insurance companies and has been ordered by over 1,200 physicians to treat over 7,200 patients. During the hearing, the Appellant's representative acknowledged he has recurrent GBM. Mr. Parks provided a clinical summary, also acknowledging the Appellant is using TTFT to treat recurrent GBM. Mr. Parks reviewed the usage history for the device and testified the Appellant has been using Optune approximately 52% of the time since 2016. While this is well below the 75% usage rate that is recommended, Mr. Parks testified that more recent guidance suggests that usage of the device at least 50% of the time is compliant. *(Hearing Record).*

The above summarized evidence may support a challenge to the LCD's conclusory language that TTFT "will be denied as not reasonable and necessary." However, the ALJ appeals process is not the proper forum for challenging an LCD. The process for reviewing LCDs is set forth in 42 C.F.R. Part 426. As is noted 42 C.F.R. § 426.310(a), LCD reviews are distinct from the appeals process set forth in 42 C.F.R. parts 405, 417, and 422 which applies to ALJ review. Therefore, while the Appellant presented convincing evidence challenging the conclusory statement in the LCD that TTFT is not reasonable and necessary, my review is limited to whether the particular facts and circumstances of this case support deviating from the LCD.

Giving the LCD substantial deference, as I am required to do, I am unable to conclude that the facts in this case support deviating from the LCD policy. The record shows the Appellant had glioblastoma first diagnosed in 2011. He received initial treatment with resection and chemotherapy. He was then diagnosed with colon cancer and what the physician describes as "recurrent GBM." After more treatment with Bevacizumab and Temozolomide, he started using the Optune device in 2014. By the time the TTFT started, the tumor had already recurred.

The treating physician, Appellant and the Supplier have failed to cite specific reasons why this Appellant was uniquely positioned, when compared to other patients with the same diagnosis, which would have compelled me to deviate from the exclusion of coverage set forth in the LCD. The treating physician has provided no detailed statement as to why TTFT was necessary in this case. There is no medical evidence in the record to explain why this particular Appellant required TTFT which would justify deviating from the LCD.

Additionally, as is noted above, the Appellant has essentially attacked the LCD citing medical literature and FDA approval for the device. The Appellant has not pointed to anything specific that is unique to this case that would warrant deviating from the LCD. While the DME-MAC Medical Directors have agreed that the device may be reasonable and necessary for newly diagnosed GBM and there is a proposed LCD that provides Medicare coverage of a newly diagnosed tumor, the proposed LCD excludes coverage for recurrent GBM. I recognize the proposed LCD is not applicable to these dates of service and has yet to become final. However, I do find it significant that the DME-MACs have only contemplated coverage for a newly diagnosed GBM and have left the existing LCD in place which precludes coverage for recurrent GBM.

In this case, the record is clear that the Appellant has a recurrent GBM. The LCD in effect applies to cases of recurrent GBM and does not allow for coverage in these instances. Even though the Appellant appears to have done well with Optune therapy and is stable per MRI, I cannot deviate from the LCD. The Appellant has been having compliance issues only using the device 52% of the time according to Mr. Park's review of the data and testimony. This falls substantially below the 75% usage rate that is recommended for the device. Therefore, because we are dealing with recurrent GBM and the Appellant has not been fully compliant with using the device, I am unable to deviate from the LCD which excludes coverage in this case. In light of the above, the documentation does not substantiate that the Optune device was reasonable and necessary treatment for recurrent GBM. As such, the item is excluded from Medicare coverage under § 1862(a)(1)(A) of the Act.

Since the item is being denied as not reasonable and necessary, it must be determined who bears the burden for payment under §1879 of the Act. There is no evidence in the record to suggest the Appellant knew, or should have been expected to know, the device would not be covered. Therefore, the Appellant cannot be held liable for payment. Pursuant to 42 C.F.R. § 411.406, the Supplier is expected to know Medicare laws and rules relating to coverage. Inasmuch as the Supplier should have known the services would not be covered, Novacure is liable for payment.

Conclusions of Law

The Appellant has not sustained his burden of proof to demonstrate TTFT was reasonable and necessary in light of the Local Coverage Determination which precludes Medicare coverage for the device. Therefore, payment shall not be made under Medicare Part B for use of the Optune device for dates of service August 7, 2018, September 7, 2018, and October 7, 2018. Novacure is liable for payment for the non-covered claims.

Order

The Medicare contractor is **DIRECTED** to process the claims in accordance with this decision.

SO ORDERED.

Dated: 6-25-19

Brian J. Butler
Administrative Law Judge

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May 8, 2019

VIA FACSIMILE 216-615-~~6735~~ 7130

Judge Brian J. Butler
Office of Medicare Hearings and Appeals
Cleveland Field Office
200 Public Square, Suite 1300
Cleveland, OH 44114-2316

RE: Response to Noridian Position Paper
ALJ Appeal No. 1-8429561876
Appellant/Beneficiary: R. Townsend
Service: E0766
Hearing Date: May 29, 2019
Our Ref. No.: 19-113

In response to the position paper submitted by Noridian, Appellant submits the following:

Prior review of information inapplicable. The dates of service at issue in the present case are from 2018. Thus, an assertion that the medical directors undertook a review in October 2015 for recurrent GBM is inapposite. The review is outdated. Fortunately, medicine and science progress. As the pre-hearing statement indicated, the compelling article on the EF-14 study (which included newly diagnosed GBM and recurrent) was published in JAMA in 2017. Since 2017, more than 50 articles have issued reporting on TTFT for both newly diagnosed and recurrent GBM.

Reference to LCD reconsideration process is inapposite. The position paper notes that there is a formal process for reviewing "if an established LCD remains clinically relevant" and "We would humbly submit that if the appellant has new clinical evidence that is persuasive, there is a formally developed pathway of requesting a review of the current LCD." Respectfully, the author of the statement appears to be unaware that (1) the DMAC medical directors, including the two Noridian medical directors, issued a statement in August indicating that they were reconsidering LCD L34823; (2) new clinical evidence was submitted and acknowledged as such by the DMAC medical directors; (3) the DMACs are undertaking a review of the literature and convened a meeting March 6, 2019 to review the same. The March 6, 2019 Contractor Advisory Committee found TTFT met Medicare coverage criteria. See https://med.noridianmedicare.com/web/jddme/policies/lcd/contractor-advisory-committee (accessed April 29, 2019). The author appears unaware that the Contractor Advisory Committee found for coverage based on the 2017 published study.

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In either event, the Appellant is not challenging the LCD through the claims appeal process. As Noridian is aware, LCDs are not binding on an ALJ and an ALJ can find for coverage in an individual case without considering the validity or invalidity of an LCD.

TTFT was widely accepted. The DMAC medical director emphasized that "Acceptance by individual health care provider, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community." In 2018, GBM had been prescribed by clinicians in every state of the United States, the District of Columbia and Puerto Rico. The evidence does not indicate that acceptance was by a "limited group of health care providers." Further, hundreds of cancer treatment centers were certified to provide the Optune System and over 1100 clinicians had prescribed it by 2018. It is used in 59 of the 62 NCI designated cancer centers.

FDA approval is relevant. The position paper also asserts that the Medicare statute contemplates no role for the FDA. Such a statement is at odds with the Secretary's regulations and statements. Indeed, page 3 of the letter indicates that under 1862(a)(1)(A) that a Medicare contractor must determine if a service is safe and effective. The Secretary has repeatedly stated that CMS adopts the FDA's determination of the safety and efficacy of a device.

> Because the FDA is charged with regulating whether devices or pharmaceuticals are safe and effective for use by consumers, generally, [CMS] will not accept a request [for coverage] for a device or pharmaceutical that has not been approved or cleared for marketing by the FDA for at least one indication . . . . Both CMS and the FDA review scientific evidence, to make purchasing and regulatory decisions, respectively. . . . Whereas ***the FDA must determine that a product is safe and effective*** as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A) of the Act. ***CMS adopts FDA determinations of safety and effectiveness***, and CMS evaluates whether or not the product is reasonable and necessary for the Medicare population. 68 Fed. Reg. 55,634 (Sept. 26, 2003) (emphasis added).

See also 75 Parallel Review of Medical Products, Fed. Reg. 57045-57048 (Sept. 17, 2010) (describing the respective roles of FDA and CMS).

Finally, Noridian improperly attempts to switch its basis of denial to the QIC's basis of denial. The purpose of contractor participation is to clarify the original basis of denial, not provide a new basis of denial. However, as noted above, the author of the position paper appears to be unaware of the position the DMAC medical directors have taken, and the developments which clearly have refuted the QIC's basis of denial. Noridian's comments on the medical records are inapposite – Noridian did not deny coverage based on the beneficiary's medical

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condition or records. This Medicare beneficiary is a long-term survivor of GBM. Medical records were submitted to support the dates of service at issue. As was noted at the MCAC meeting, any use of TTFT improves outcomes. Thus, a beneficiary who uses TTFT 60% does better than a beneficiary who uses TTFT 50%, and a beneficiary who uses 70% does better than a beneficiary who uses 60%. In either event, given that the life expectancy for an individual with recurrent GBM is six months, and Mr. Townsend has been using TTFT since April 2014, clearly Mr. Townsend has benefited substantially though his use of TTFT regardless of whether he met a "goal."

In short, Noridian's position paper does not reflect consideration of relevant material facts and misstates the law. Appellant respectfully requests approval of these dates of service for a condition for which no cure exists, which continues to afflict Appellant and which has been effectively and remarkably managed by TTFT.

Very truly yours,

Debra M. Parrish for R. Townsend

Cc: Noridian
Novocure, Inc.

noridian
Healthcare Solutions

Medicare DME
Attn: DME ALJ
PO Box 6740
Fargo ND 58108-6740

May 6, 2019

The Honorable Brian J. Butler
U.S. Administrative Law Judge
Office of Medicare Hearings and Appeals
Cleveland Field Office
200 Public Square, Suite 1300
Cleveland, OH 44114-2316

ALJ Hearing Number 1-8429561876 (Hearing to be held on May 29, 2019).

Re: Novocure, Inc

Dear Judge Butler,

Introduction

The purpose of this paper is to provide a global argument for the the rationale used by Noridian Health Services (NHS), a Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for Jurisdictions A and D, to deny payment of claim(s) for the Novo TTF-100A System (E0766) for submitted claims by Novocure Inc, hereby known as the "appellant".

Argument

The claims for the Novo TTF-100A System (E0766)) for dates of service in question were denied pursuant to Section 1862(a)(l)(A) of the Act and Medicare regulations and Local Coverage Determination (LCD) L34823.

Authority

Title XVIII § 1862(a)(I)(A) of the Social Security Act, which governs coverage for items and services that are "reasonable and necessary".

68 Fed. Reg. 63,693.

LCD L34823.

CMS Pub 100-08 Medicare Program Integrity Manual (MPIM), Chapter 13.5.1, which reviews reasonable and necessary provisions in LCDs.

CMS Pub 100-08 Medicare Program Integrity Manual (MPIM), Chapter 13.7.1, which reviews evidence supporting LCDs.

Discussion

Glioblastoma or glioblastoma multiforme (GBM) is an aggressive brain cancer. It is more common in men, and persons older than age 50. Approximately 3 per 10,000 people develop the disease a year. Thus, it is a rare cancer, whose public awareness has been raised with the death of senators Ted Kennedy and John McCain. The initial signs and symptoms are usually non-specific and may include headaches, personality changes, seizures and symptoms like those of a stroke. The symptoms usually worsen rapidly. The standard of care is surgery, followed by chemotherapy with temolozomide, and radiation. Recurrence is common despite treatment. The length of survival following diagnosis is 12 to 15 months. Treatment may slow progression of the cancer and reduce symptoms. However, there currently is no cure.

In 2011, the FDA approved Novocure transducer arrays termed "Tumor Treating Fields" (TTF) for the treatment of recurrent glioblastoma. There was no FDA indication supporting the use for newly diagnosed glioblastoma and thus Medicare could not even consider coverage. In October of 2015, the FDA did approve Novocure for the treatment of newly diagnosed glioblastoma. **However, although FDA approval is necessary, it is not sufficient by itself for purposes of Medicare coverage or reimbursement.** In *Almy v. Sebelius*, 679 F.3d 297 (2012), the 4th Circuit noted: "The Medicare statute clearly vests the Secretary with the authority to interpret when a device is "reasonable and necessary," and therefore eligible for coverage under Part B. The statute contemplates no role for the FDA, which is charged with applying the standards of the Federal Food, Drug, and Cosmetic Act, not the Medicare statute. The FDA examines "the labeled use of a device only," concentrating its review on the safety of a device, whereas Medicare review "focus[es] on ... a device under average conditions of use" to determine whether the device meets the broader requirement of the Medicare statute that a device be "reasonable and necessary." 54 Fed. Reg. 4307."

In *Heckler v. Ringer*, 466 U.S. 602, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984), the Supreme Court held that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions."

In October of 2015, the DME MACs reviewed the clinical literature, and developed and posted a Local Coverage Determination (LCD L34823) indicating that TTFT was non-covered for beneficiaries with GBM. We have attached the DME MACs formal "Response to Comments" regarding the LCD.

Advances in medical care and treatments can occur, and thus, there is a formal process of reviewing if an established LCD remains clinically relevant. The process is called an LCD Reconsideration request, and the Secretary has published sub-regulatory guidance in *CMS Pub 100-08 Medicare Program Integrity Manual (MPIM), Chapter 13,* regarding how anyone can submit a request. We would humbly submit that if the

appellant has new clinical evidence that is persuasive, there is a formally developed pathway of requesting a review of the current LCD.

MPIM § 13.5.1, Reasonable and Necessary Provisions in LCDs states:

A*n item or* service may be covered by a contractor *LCD* if:

> It is reasonable and necessary under 1862(a)(1)(A) of The Act. Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
>
> - Safe and effective;
> - Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
> - Appropriate, including the duration and frequency that is considered appropriate for the *item or* service, in terms of whether it is:
>
> o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;
>
> o Furnished in a setting appropriate to the patient's medical needs and condition;
>
> o Ordered and furnished by qualified personnel;
>
> o One that meets, but does not exceed, the patient's medical need; and
>
> o At least as beneficial as an existing and available medically appropriate alternative

MPIM 13.7.1 further instructs contractors to base LCDs on the ***strongest evidence available at the time the determination is issued***. In order of preference, this includes:

Published ***authoritative evidence*** *derived from definitive randomized clinical trials or other definitive studies, and*

General acceptance by the medical community (standards of practice)*, supported by sound medical evidence based on:*

> *Scientific data or research studies published in peer-reviewed medical journals;*
> *Consensus of expert medical opinion (i.e., recognized authorities in the field); or*

Medical opinion derived from consultations with medical associations or other health care experts.

MPIM 13.7.1 cautions that: "***Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community.*** Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached". [Emphasis added]

It has come to our attention that some attorneys are stating that the LCD did not provide a summary of the evidence considered or a rationale for the determination. These requirements that are being noted (CR 10901) were effective for LCDs that were developed after January 1, 2019. Therefore, they were not applicable to the LCD L34823 which was finalized in August of 2014.

The case files were reviewed. Noridian agrees with the reconsideration analysis as stated in the reconsideration letter. The submitted documentation indicated the beneficiary was started on TTFT therapy for recurrent glioblastoma. Physician progress notes from April 13, 2016, to August 23, 2018 were submitted. The notes documented the diagnosis of glioblastoma in November of 2011. The beneficiary was lost to follow-up twice and began TTFT in April 2014. Compliance was documented as less than goal.

On the dates of service for the claims in appeal, they were denied as not "reasonable and necessary" according to the published LCD in effect.

Respectfully,

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